



NOV - 8 2010

Philip Johnson, Esq.
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One Johnson & Johnson Plaza
New Brunswick, NJ 08816
Attn: Thomas J. Dodd

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,317,016

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,317,016, claims of which cover the human drug product DORIBAX® (doripenem), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,025 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of a request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,025 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of Sept. 4, 2009 (74 Fed. Reg. 45863). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1 \\ &= 1,746 - 0 - 0 - \frac{1}{2} (1,442 - 0) \\ &= 1,025 \text{ days (2.8 years)}\end{aligned}$$

Since the regulatory review period began, after the patent issued (May 31, 1994), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

¹ Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2} (\text{TP} - \text{PGTP})$.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

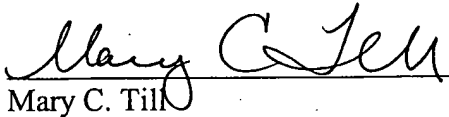
U.S. Patent No.:	5,317,016
Granted:	May 31, 1994
Original Expiration Date ² :	August 14, 2012
Applicant:	Yasuhiro Nishitani et al.
Owner of Record:	Shionogi Seiyaku Kabushiki Kaisha
Title:	Pyrrolidylthiocarbapenem Derivative
Product Trade Name:	DORIBAX® (doripenem)
Term Extended:	1,025 days
Expiration Date of Extension:	June 5, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Hatch-Waxman PTE	By FAX:	(571) 273-7755
	Commissioner for Patents		
	P.O. Box 1450		
	Alexandria, VA 22313-1450.		

²Subject to the provisions of 35 U.S.C. § 41(b).

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Tilk

Legal Advisor

Office of Patent Legal Administration

Office of the Associate Commissioner

for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

RE: DORIBAX® (doripenem)
Docket No.: FDA-2008-E-0266

Attention: Beverly Friedman